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Patent Application for

OPTICAL DISPLACEMENT SENSOR FOR INFUSION DEVICES

Inventors:

Marc A. Mandro
199 Woodhill Hooksett Rd.
Bow, NH 03304

Larry B. Gray
19 Iris Dr.
Merrimack, NH 03054

Attorney docket number: 1062/D78

Attorneys:
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110-1618
Tel: (617) 443-9292
Fax: (617) 443-0004

Optical Displacement Sensor for Infusion Devices

The present application claims priority from US Provisional Application 60/398,259, filed July 24, 2002, which is incorporated herein by reference.

Field of the Invention

The present invention pertains to optical sensors for monitoring the source and/or amount of a substance, such as a medicinal agent, delivered by a delivery device.

Background Art

Devices, such as pumps or manual pens, used for delivering substances, such as drugs or insulin, from a local reservoir into the body of a patient are prone to problems that may impede the intended delivery rate of the substance. Such problems may include clogging, mechanical sticking, or misidentification of the administered substance. It is thus desirable that the source of the delivered substance be positively identified by the delivery device, that the proper loading of the substance reservoir be verified, that the instantaneous volume of substance in the reservoir be ascertainable, and that both the rate of delivery and the precise volume of remaining liquid be accurately monitored. Prior use of an optical monitor for similar applications, such as described in U.S. Patent no. 4,498,843 to Schneider, et al., has been limited to measurement of delivery rate. It is, furthermore, desirable that the aforesaid functions be provided both accurately and cost effectively.

Summary of the Invention

In accordance with preferred embodiments of the invention, there is provided a displacement sensor for a dispensing device of the type that has a translating piston. The sensor has a plunger rod coupled to the piston, and the plunger rod has an encoded pattern of encoding features. A light source illuminates the encoded pattern and a detector array detects light from the illuminated encoded pattern and generates a detector signal such that, on the basis of the detected signal, a processor determines a

displacement of the plunger rod relative to a fiducial reference position. The delivery rate of a substance dispensed by the device may also be determined. Additionally, the encoded pattern may serve to identify a reservoir type characterized, for example, by a distinct concentration of a therapeutic agent to be delivered by the dispensing device.

Brief Description of the Drawings

FIG. 1 shows the fundamental constituents of a prior art medical fluid pump;

FIG. 2 is a schematic depiction of an optical linear encoder for delivery of a liquid agent in accordance with preferred embodiments of the present invention;

FIG. 3 is a perspective view of a medical fluid pump including an optical linear encoder in accordance with an embodiment of the present invention; and

FIG. 4 is an exploded view of an embodiment of an optical linear encoder in accordance with the invention as applied to a medical fluid pump.

Detailed Description of Specific Embodiments

Major components of a pump for delivering a therapeutic agent to the body of a patient are described with reference to Fig. 1. A medication reservoir 11, typically cylindrical in shape, is retained within a housing 16 and contains a liquid agent to be delivered to a patient via a delivery tube 18 and a hypodermic needle (not shown). The liquid agent contained within the reservoir is impelled out of the reservoir at a determined rate by linear motion of a piston 30 along a direction 8 coaxial with the axis of the reservoir. The piston is driven by a plunger rod 12 that is driven, in turn, at a prescribed rate, by a motor (not visible) coupled to a screw drive 14 via a gear reduction drive. It is to be understood that the present invention may advantageously be applied for delivery devices other than pumps, such as insulin pens, as well as for the delivery of various fluids or other substances that may be medicating agents or other substances. The description of a pump and in terms of delivery of a therapeutic agent to a patient is without limitation and by way of example only. Embodiments of the present invention may also advantageously be applied, for example, for delivery of purification agents into a water supply. The fluid to be delivered is typically a liquid, however the delivery of

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other substances is also within the scope of the present invention as described herein and as claimed in any appended claims.

The rate at which the pump motor is driven in order to impel the piston to deliver the liquid agent at a prescribed rate is governed by a processor on the basis of the cross section of the reservoir (i.e., the volume of agent expelled per unit linear motion of the piston) and the concentration of agent within the fluid contained in the reservoir.

In accordance with preferred embodiments of the present invention, an optical linear encoder is used to determine both the absolute position and rate of motion of the plunger rod. Additionally, since the reservoir and piston may be supplied to the user as an integral unit, additional information may be encoded on the plunger rod, as described in greater detail below.

It is desirable, in particular, that four functionalities be provided by a sensor used in conjunction with fluid delivery:

a. monitoring delivery accuracy;

b. identifying a characterizing feature of the reservoir (such as to its contents);

c. determining the volume of fluid remaining in the reservoir; and

d. verifying proper loading of the reservoir.

It is particularly advantageous if, as in accordance with a preferred embodiment of the present invention, all of the above functionalities may be provided by a single sensor.

If, as in preferred embodiments of the present invention, the reservoir identification is associated with the concentration in the fluid of a drug to be delivered by the infusion device, then a programmed dose may be converted into a linear distance.

In preferred embodiments, transmission-type encoding is employed, however, any analogous reflection-type encoding is within the scope of the invention. Referring to Fig. 2, piston **30** is driven along axis **32** so as to impel the liquid contents of reservoir **34** out orifice **36**. Piston **30** is propelled by plunger rod **38**, which advances as lead screw **40** is rotated. In the preferred embodiments of transmission-type encoding, a light source **42** and detector **44** are disposed on opposite sides of plunger rod **38**. As used herein, the term "detector" may refer, as the context demands, to an array of detectors. The detector

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or detector array may also be referred to, herein, as an "image sensor" or an "image array." The term "detector assembly" may refer to a detector or array of detectors along with associated preamplification and signal-conditioning electronics. Plunger rod **38** is encoded, in such embodiments, by features **46** that may be recognized by detector **44**.

In accordance with one embodiment of the invention, encoding features **46** are slots orthogonal to the axis of travel **32** of the piston are scored into plunger rod **38**. In alternate embodiments, round (or otherwise shaped) holes, or slots parallel to axis **32**, wedges, or other light-transmitting features may be employed, all the above provided solely for purposes of example and without limitation. Slots **46** or other optically transmissive features may be fully optically transmissive or may, alternatively, modulate the some detectable characteristic of light (designated by dashed lines **48**) transmitted between source **42** and detector **44**. Transmissive features **46** may thus employ filters (of neutral density or otherwise), thereby modulating the intensity and/or spectral characteristics of the transmitted light, or may employ polarizers or retardation plates, thereby modulating the polarization or phase of the transmitted light. All such techniques for encoding transmitted light are within the scope of the present invention as described herein and as claimed in any appended claims.

In accordance with preferred embodiments of the present invention, detector **44** advantageously spans merely a portion of the region of plunger rod, as described in greater detail below, however any relative sizes of the detector **44** and plunger rod **38** are within the scope of the present invention.

The path of light from light source **42** to detector **44** may be one of direct transmission through plunger rod **38** as shown. Alternatively, encoding **46** may be detected in reflection by suitable placement of detector **44** on the same side of plunger rod **38** as light source **42**. Light source **42** may be an array of light-emitting-diodes (LEDs), in which case diffuser **50** may be employed. Other sources of diffuse light, such as electro-luminescent light sources may also be employed. Diffuser **50** may include multiple diffusion stages, as shown. Illumination may also be provided by undiffused light. Illumination may be transmitted through encoding **46** directly onto detector **44**, as shown, or, in other embodiments of the invention, a reflective light path or transfer of illumination pattern via optical fibers or other light pipes may be employed. Intervening

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optics such as a lens, microchannel plate, etc., may also be provided within the optical path, within the scope of the present invention.

A housing **60** for embodying the substance dispenser components of Fig. 2 is shown in perspective view in Fig. 3. Motor drive **62** is hidden from view but shown as a dashed component. Reservoir **34**, with plunger rod **38** in extension therefrom, is shown prior to insertion into the housing. The exploded view of Fig. 4 shows drive module **70**, containing drive motor **62** and reservoir barrel **72**, light source module **42**, diffuser **50**, detector **44**

Detector **44** may be comprised of multiple detector resolving elements, and may be realized as a CMOS linear image sensor, for example, or a charge-coupled device (CCD) array, for another example. Many formats may be employed advantageously. Within the scope of the present invention, the detector elements may be linearly or two-dimensionally arrayed, and such arrays may be realized, if design considerations so require, by both linear and lateral stacking of detector arrays.

The image formed on detector **44** is analyzed, by directing the output signal of detector **44**, via analog-to-digital converter **54**, to processor **56**, in accordance with various algorithms to be discussed in detail below. Pixel size and number are optimized with respect to resolution and resources demanded of processor **56**.

By means of employing an encoding pattern that does not repeat, positioning of the moveable plunger rod with respect to the fixed optical assembly (taken to comprise both the illuminating and detecting optics) may advantageously be determined absolutely. Alternatively, the slot pattern or other encoding pattern may be repeated one or more times, thereby allowing translation to be encoded over large travel distances. In embodiments wherein the encoding pattern defines a non-unique current position of the plunger rod, plunger rod **38** may be driven to a fiducial position **52**, such as a limit stop, in order to establish a reference from which to count repeats and to establish an absolute present position of the plunger rod relative to the fiducial position.

In preferred embodiments of the invention, detector **44** is realized as a 512-pixel linear array, with pixel resolution of approximately 16 μm. Detector **44** is positioned along and parallel to the line of travel of plunger rod **38**, beginning substantially at the

end of lead screw **40**. Particularly when focusing optics are not employed, it is preferred that detector **44** should be positioned in close proximity to plunger rod **38**.

In a preferred embodiment of the invention, the spacing of plunger rod slots **46** is chosen in such a manner that any two adjacent spaces form a unique sequence. Additionally, the sum of the lengths of any two spaces is always greater than the distance between any two adjacent slots, thus, in case a slot becomes unintentionally blocked, the anomaly may be detected and not mistaken for another absolute position. Additionally, it is provided that either three or more slots are visible to the image sensor at any one time, or else the end of the rod and at least one slot are visible to the image sensor at any given time.

The three versions of slot spacings, given in inches in Table I, meet the preferred criteria discussed in the foregoing paragraph. The spacing of any two adjacent spaces may be coded to uniquely define a version of the reservoir, so that different concentrations of medicinal agent may be supplied and distinguished. Characteristics of the reservoir version that may be identified in this manner include, without limitation, the inner diameter of the reservoir, and the composition (plastic or glass, for example) of the wall of the reservoir. Additionally, the distance between the end of the plunger rod and the last slot may uniquely identify a reservoir version, so that, in case no more than one slot is within the field of view of the image sensor, the reservoir version may be uniquely identified.

Table I: Slot To Slot Distance (inches)										
Version	Slot 1 to Slot 2	Slot 2 to Slot 3	Slot 3 to Slot 4	Slot 4 to Slot 5	Slot 5 to Slot 6	Slot 6 to Slot 7	Slot 7 to Slot 8	Slot 8 to Slot 9	Slot 9 to Slot 10	Slot 10 to end
#1	0.084	0.096	0.084	0.084	0.060	0.096	0.108	0.060	0.060	0.110
#2	0.072	0.060	0.072	0.096	0.096	0.072	0.084	0.108	0.072	0.095
#3	0.060	0.108	0.096	0.060	0.084	0.072	0.072	0.108	0.084	0.080

To create an image, all pixels of detector **44** are reset. Then light source **42** is flashed such that light is emitted for a specified duration of time. Variable-duration

exposure times may be employed, such that longer times are used when slots are being viewed, whereas shorter times are used when the end of the plunger rod is being viewed. Exposure times of 5 ms for slots and 0.7 ms for the end of the rod have been found to be satisfactory. The signal from detector **44** is read, with values for each pixel stored by processor **56** in an array and interpreted using one or more algorithms.

In the embodiment to which Table I refers, there is a small portion of the travel where only two slots are visible (9 and 10) as well as the end of the rod. The normal means of identifying the syringe using two adjacent spaces cannot be used since only a single spacing is available. The alternate means of identifying the syringe using the distance between the end of rod and the last slot cannot be used because the end is too close to the edge of view to be detected using the sliding window algorithm. Thus a third means of identifying the syringe is used when only two slots are visible and the end of the rod position cannot be measured but is visible. This third method relies on a unique slot-9-to-slot-10 spacing.

In accordance with one exposure procedure, the light is left on. Then, the detector reads and resets each pixel in sequence at a specific clock rate. The array is then read twice, the first read serving to reset the pixels. The second read of each pixel thus occurs "n" times the clock period since that pixel was reset.

In a preferred mode of operation, measurements of plunger rod position are made once per basal step of the piston, during delivery of a bolus, and during priming. In between measurements, image sensor power may be removed, since the position determination is absolute.

In accordance with embodiments of the invention, various algorithms may be employed in order to detect the position of transmitted light peaks to within specified resolution. One Peak Detection Algorithm employs a sliding window split into two equal halves. The values of pixels in each half are summed, and the sums subtracted from each other. The difference between the signals in the two halves is calculated for all possible positions of the sliding window, giving a measure of the slope of the intensity curve. As zeroes occur at local extrema, whether peaks or valleys, the sign of the difference value as the zero point is approached is used to distinguish between these two cases. Other peak and edge identifying algorithms are within the scope of the present invention.

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Movement of the peaks may be used to track the accuracy of plunger rod movement and thus delivery of the liquid agent being driven out of the reservoir.

In accordance with further embodiments of the invention, the spacing between slots can be resolved to finer increments than the pitch of detector **44** by storing the A/D pixel values in a software array with power-of-2 more elements than the sensor array. For example, resolution would be increased eightfold if a 512 pixel image was stored in a 4096 element software array. This is done by storing the 1st sensor array value in each of the 1st eight software array elements. The 2nd sensor array value is stored in each of the next eight software array elements, and so on.

Alternatively, by reading every n^{th} pixel, where n is a power of 2, and storing these values in a software array with the same number of elements as the sensor array, image read times can be decreased without adversely affecting the slot to slot measurement resolution.

Having thus described various illustrative embodiments of the present invention, some of its advantages and optional features, it will be apparent that such embodiments are presented by way of example only and are not by way of limitation. It is to be understood that the teachings of the present invention may be applied to the metered delivery of fluids for other applications, such as the delivery of chemicals to a supply of potable water, to name merely a single example. Those skilled in the art could readily devise alternations and improvements on these embodiments, as well as additional embodiments, without departing from the spirit and scope of the invention. All such modifications are within the scope of the invention as claimed.